



1620 I Street, NW Suite 800  
Washington, DC 20006  
(202) 833-9070  
FAX (202) 833-9612

Alice E. Till, Ph.D.  
President

March 13, 1999

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Drug Information Branch (HFD-210)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Draft Guidance for Industry on SUPAC-SS: Nonsterile Semisolid Dosage Forms, manufacturing Equipment Addendum [Docket No. 95D-0349]

Dear Sir or Madam:

On behalf of the Science Committee of the Generic Pharmaceutical Industry Association (GPIA), I would like to submit comments to you on "Draft Guidance for Industry on SUPAC-SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum", 64 FR 518, January 5, 1999.

GPIA is comprised of the manufacturers and distributors of generic medicines, as well as the providers of technical services and goods to these firms. Several of our members will be directly impacted by implementation of the subject guidance.

As with the equipment addendum to other SUPAC documents, GPIA generally supports the agency's efforts to create this detailed summary of equipment. Furthermore, GPIA agrees with the content of the draft with respect to a) the identification of the categories of processing steps, and b) the definition and grouping of each class and subclass of equipment.

Some clarification is requested, however, and some edits are suggested. Additionally, other equipment examples are offered for inclusion in the various tables.

Add the following italicized items:

- III. Mixing
  - A. Definitions
    - 2. Operating Principles
      - c. *High-pressure Ultrasonic Mixing/Homogenizing: Mixing/homogenizing that employs high pressure and ultrasonic cavitation forces. The material is pumped through a specially designed orifice where it is subjected to shear, pressure and ultrasonic forces.*
  - B. Equipment Classification
    - 3. *High-pressure Ultrasonic Mixer/Homogenizer: No subclasses have been identified.*

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Table 3

Subclass Anchor/Sweepgate	<i>Olsa</i>
Subclass Dispersator	<i>Admix Rotoshear</i>
Subclass Ultrasonic	<i>Sonolator</i>

IV. Emulsification

A. Definitions

2. Operating Principles

- iv. *Employing the energy of ultrasonic vibration as a means of creating stable emulsions.*

B. Equipment Classification

3. *High Shear Emulsifiers*

- *Ultrasonic*

Table 4

Subclass Rotor Stator	<i>Becomix</i> <i>Maltomat</i> <i>Lee Trimix Turbo Shear</i>
Subclass Ultrasonic	<i>Sonolator</i>

Table 5

Subclass Vacuum Vessel	<i>Olsa</i> <i>Becomix</i> <i>Maltomat</i>
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VII. Packaging

A. Definitions

2. Operating Principles

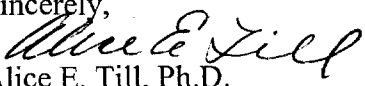
- c. . . and/or agitation *and/or* circulation.
- c. . . peristaltic, *vacuum*, or piston pump.

Table 9

Subclass Mechanical/Crimping	<i>Kalish</i>
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We would appreciate your consideration of these comments as the guidance is finalized.

Sincerely,

  
Alice E. Till, Ph.D.  
President

Cc S. Hyden, Chair GPIA Science Committee  
D. Miran, Chair Taskforce on Nonabsorbed Drugs